

REMARKS

The Amendments

Claim 47 is amended to delete “or fragment thereof.” Claim 47 is also amended to recite higher level of protein expression; support for the amendment can be found, for example, at page 7, lines 29 and 30. Claim 47 is further amended to provide clarity.

No new matter is added in the amendments. The Examiner is respectfully requested to enter the amendments.

The Response

35 U.S.C. §112 Second Paragraph Rejection

Claims 47-51 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is traversed in parts and overcome in parts in view of the claim amendment.

The Examiner states that Claim 47 and the dependent Claims 48-51 are indefinite for the recitation of the phrase, “wherein a difference in said protein expression indicates that the first individual has breast cancer.” The Examiner states that it is confusing how one can derive at a definitive conclusion that an individual has cancer based on expression analysis when the specification discloses less than 100% correlation of the claimed marker to cancers (Figure 3).

Claim 47 has been amended to recite a method of detecting breast or colorectal cancer. A method of detecting cancer does not require “100%” sensitivity or specificity. Figure 3 shows the relative amount of expression of CZA8 in various samples of breast cancer tissue, colorectal cancer tissue and normal tissue types. Figure 3 shows that many breast and colorectal cancer tissue samples have a high expression level of CZA8; whereas normal tissue samples have a significantly lower expression of CZA8. Figure 3 confirms that the present invention provides a method for detecting breast or colorectal cancer.

Therefore, the 35 U.S.C. §112, second paragraph rejection of Claims 47-51 should be withdrawn.

35 U.S.C. §102(e) Rejections

Claims 47, 50, and 51 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Penn, *et al.*, U.S. 2002/0048763 A1. The reference application was filed on May 23, 2001, which claims priorities to multiple applications including two provisional applications filed on February 4, 2000 and May 26, 2000, respectively. Applicants do not agree that the reference application is entitled to the early priority dates as claimed. However, to further prosecution, Applicants have amended the claims to delete “or fragment thereof.”

Penn, *et al.* disclose that the human genome-derived single exon nucleic acid probes and microarrays can be used for predicting, diagnosing, grading, staging, monitoring and prognosing diseases of human breast, particularly those diseases with polygenic etiology [1367]. Penn *et al.* disclose a single exon probe of SEQ ID NO: 30857 that encodes an amino acid sequence of SEQ ID NO: 38497, which has 72 amino acid residues. In the present invention, the 865 amino acid sequence of SEQ ID NO: 2 and the 855 amino acid sequence of SEQ ID NO: 4 contain the 72 amino acid residues (SEQ ID NO: 38497) disclosed in Penn, *et al.* Although it may be construed that Penn, *et al.* have disclosed a fragment of SEQ ID NO: 2 or 4, it is clear that Penn, *et al.* do not teach a sequence of CZA8 gene. Therefore, by amending Claim 47 to delete “or fragment thereof,” Claims 47, 50 and 51 are not anticipated by Penn, *et al.*

35 U.S.C. §103 Rejection

Claims 48 and 49 are rejected under 35 U.S.C. §103(a) as being unpatentable over Penn, *et al.* U.S. 2002/0048763 A1) in view of Keyomarsi, *et al.*, U.S. Patent No. 5,543,291. The rejection is overcome in view of the claim amendment.

The primary reference, Penn, *et al.*, does not teach or suggest a sequence of CZA8 gene. The addition of Keyomarsi, *et al.* does not solve the deficiency of the primary reference.

Therefore, the Examiner is requested to withdraw the 35 U.S.C. §103(a) rejection of Claims 48 and 49.

Double Patenting Rejection

Claim 50 is provisionally rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of Claim 7 of a copending Application No. 09/608,821.

The 09/608,821 Application has been issued as U.S. Patent No. 6,566,502 on May 20, 2003. In view of the amendment of Claim 47, the claims in the present application are not identical to those of the '502 Patent. Therefore, the 35 U.S.C. §101 rejection of Claim 50 should be withdrawn.

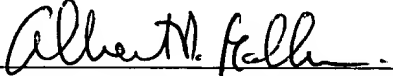
Applicants are submitting herewith a Terminal Disclaimer to obviate any potential obviousness-type double patenting rejection.

CONCLUSION

Applicants believe that the application is in good and proper condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 463-8109.

Respectfully submitted,

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